IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	**REDACTED PUBLIC VERSION**
Plaintiffs,	)	C.A. No. 06-286-GMS
v.	)	
BARR LABORATORIES, INC.,	)	
Defendant.	)	

PLAINTIFFS' OPPOSITION TO BARR LABORATORIES, INC.'S MOTION *IN LIMINE* TO EXCLUDE AVENTIS' ASSERTIONS OF ANY INVENTION DATES LATER THAN MAY 1, 1992

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Dated: May 2, 2008

PRELIMINARY STATEMENT

Throughout this litigation, Plaintiffs have maintained that the clinical trials of the claimed invention were an "experimental use," and not a "public use" under § 102(b). Knowing this, Barr admits it was elated when, in response to an interrogatory, Plaintiffs provided an erroneous reduction-to-practice date that preceded the clinical trials, which would in Barr's view undercut Plaintiffs' experimental use assertion. As counsel for Barr stated at the pre-trial conference, "we got a date that we thought was great for us, frankly." (Ex. A at 55:21-22.) Barr then adopted a strategy to ambush Plaintiffs at trial, withholding notice of its reliance on the date, in violation of Barr's duty to provide a complete response to one of Plaintiffs' contention interrogatories.

In its motion, Barr asks this Court to preclude Plaintiffs from correcting their reduction-to-practice date, the determination of which is an issue of law for the Court to decide, based on underlying facts. *See z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007). There is no dispute that Plaintiffs produced all of the relevant factual evidence necessary to determine the reduction-to-practice date; the only dispute is whether Plaintiffs should be allowed to correct this legal conclusion in view of Barr's strategy of surprise.

ARGUMENT

I. Plaintiffs' Supplemental Response to Barr's Interrogatory No. 7 is Appropriate and Proper Under FRCP 26(e)

Rule 26(e) imposes a "duty seasonably to amend a prior response to an interrogatory . . . if the party learns that the response is in some material respect incomplete or incorrect . . . ." FED. R. CIV. P. 26(e)(2). In this case, Plaintiffs amended their response to Barr's Interrogatory No. 7 within two weeks of learning that they had provided a legally erroneous reduction-to-practice date. Plaintiffs did not become aware of their error until they reviewed Barr's Proposed Findings of Fact and Conclusions of Law, served on April 7, 2008. There, Barr asserted for the

first time that Plaintiffs could not argue that the clinical trials were an experimental use because Plaintiffs asserted a reduction-to-practice date that preceded the clinical trials. Plaintiffs reviewed the cases Barr cited and conducted additional legal research, which revealed a recent case stating that reduction to practice of a pharmaceutical formulation and method of treatment is "not achieved simply upon conception and initial testing" of the formulation; rather, such inventions are reduced to practice only after Phase 3 clinical trials. *Astrazeneca AB v. Mylan Labs., Inc. (In re Omeprazole Patent Litig.)*, 490 F. Supp. 2d 381, 506 (S.D.N.Y. 2007). Thus, on April 21, 2008, Plaintiffs amended their response to Barr's interrogatory. (Ex. B.) In similar circumstances, other courts have found amendment of contention interrogatory responses to be proper. *See, e.g., Engineered Prods. Co. v. Donaldson Co.*, 165 F. Supp. 2d 836, 858-59 (N.D. Iowa 2001) (allowing amendment of asserted reduction-to-practice date that did not rely on any new facts); *Prins v. Int'l Tel. & Tel. Corp.*, 757 F. Supp. 87, 94-95 (D.D.C. 1991) (allowing post-discovery amendment of contention interrogatory response).

Any controversy over the timing of Plaintiffs' amended response could – and should – have been prevented by Barr. Specifically, Barr failed to provide a complete answer to Plaintiff's Interrogatory No. 5, served on September 8, 2006, which required Barr to provide a detailed explanation of "all facts and evidence supporting the contentions in Barr's Third Affirmative Defense and Counterclaims I and III that the patents-in-suit are 'invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112' . . . ." (Ex. C.) Plaintiffs provided their erroneous reduction-to-practice date to Barr on December 29, 2006. Since then, Barr twice amended its answer to Plaintiffs' Interrogatory No. 5 without providing any indication that it was relying on Plaintiffs' asserted reduction-to-practice date. (Ex. D; Ex. E.) Finally, on January 25, 2008, Barr cryptically cited "Plaintiffs' Responses and Second and Third Supplemental

Responses to Interrogatory No. 7" as a document where "additional support" might be found. (Ex. F at 14.) Even in this delayed response, Barr utterly failed to provide the "detailed explanation" of its invalidity position required by any fair reading of Plaintiffs' contention interrogatory.

Barr argues that Plaintiffs "did not even assert [experimental use] until January 31, 2008," when Plaintiffs served the Expert Report of Michael A. Kaliner, which addresses experimental use. (Barr Mot. at 5.; Ex. G.) However, that argument is belied by Barr's supplemental interrogatory response six days earlier. In addition, Barr's interest in Plaintiffs' asserted reduction-to-practice date throughout discovery reflects its awareness of Plaintiffs' experimental use assertion. Notwithstanding Barr's arguments to the contrary, Barr asked Plaintiffs' fact witnesses numerous questions about reduction to practice at their depositions. (*See, e.g.*, Ex. H; Ex. I; Ex. J; Ex. K.) In fact, as Barr knows, Plaintiffs have maintained that the clinical trials were an experimental use since at least 1998, during the prosecution of the patents-in-suit. (*See* Ex. L.) In any event, Barr did not even disclose its defense to Plaintiffs' assertion of experimental use upon receiving Dr. Kaliner's expert report, which was served before expert depositions began. Had Barr done so, it could have mitigated the prejudice it now claims.

As soon as Barr decided to rely on Plaintiffs' reduction-to-practice date as a defense to Plaintiffs' assertion of experimental use, it was incumbent upon Barr to disclose that reliance in response to Plaintiffs' Interrogatory No. 5. Instead, Barr chose to "game" the discovery process and ambush Plaintiffs on the eve of trial.

II. Excluding Plaintiffs' Evidence That the Clinical Trials Were an Experimental Use Would Be an Unduly Harsh Sanction Under FRCP 37(c)(1)

If Barr is correct that experimental use cannot occur after reduction to practice (which Plaintiffs dispute), then precluding Plaintiffs from amending their asserted reduction-to-practice

date would be tantamount to excluding all of Plaintiffs' evidence on experimental use – an extreme sanction under Rule 37(c)(1). "[T]he exclusion of critical evidence is considered an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence." *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977) (internal citation and quotations omitted). Third Circuit courts consider five factors in particular when determining whether to exclude evidence under Rule 37(c)(1): "(1) the prejudice or surprise to a party against whom the evidence is offered; (2) the ability of the injured party to cure the prejudice; (3) the likelihood of disruption to the trial schedule; (4) bad faith or willfulness involved in not complying with the disclosure rules; and (5) the importance of the evidence to the party offering it." *Bridgestone Sports Co. v. Acushnet Co.*, No. 05-132, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007) (Farnan, J.) (citing *Meyers*, 559 F.2d at 905).

First, Barr cannot claim that it was surprised by Plaintiffs' assertion of experimental use, since Barr's actions demonstrate its awareness of that assertion. Additionally, Barr's claims of prejudice are exaggerated. Barr argues that allowing Plaintiffs to correct their asserted reduction-to-practice date "would require Barr to take extensive additional discovery." In fact, however, Barr has already asked Plaintiffs' witnesses numerous questions about reduction to practice and the clinical trials. (*See, e.g.*, Ex. H; Ex. I; Ex. M.) Barr has not offered a single concrete example of a line of questioning that it would have pursued if Plaintiffs had amended their reduction-to-practice date earlier. Moreover, Barr took no steps to mitigate any prejudice.

Second, any prejudice can easily be cured by limited additional discovery. Plaintiffs have produced all relevant documents relating to reduction to practice and experimental use, and have offered numerous fact witnesses for deposition on these subjects. Thus, Barr has had the

relevant facts all along. To the extent that Barr chose not to pursue certain lines of questioning at depositions, limited additional depositions would cure any potential prejudice.

Third, there is no need to delay the trial. As established above, Barr has already conducted sufficient discovery into reduction to practice. Barr has all of the relevant documents and asked numerous questions about the subject at depositions. Similarly, Barr's argument that allowing Plaintiffs' amendment would change the scope of available prior art under § 102 falls flat. An amendment to the reduction-to-practice date does not affect what qualifies as prior art under § 102(b). And if Barr wanted to assert intervening prior art under § 102(a), (e) or (g), it always could have asserted that art and contended reduction to practice occurred afterward.

Fourth, Barr has offered no evidence of "bad faith or willfulness" on Plaintiffs' part – because there is none. *See Dudley v. South Jersey Metal, Inc.*, 555 F.2d 96, 98-100 (3d Cir. 1977) (finding exclusion of evidence improper in the absence of bad faith). If any party has acted in questionable faith in this case, it is Barr, who improperly concealed its reliance on Plaintiffs' erroneous reduction-to-practice date.

Finally, Plaintiffs' evidence of experimental use is critically important to its ability to defend against Barr's assertion that the clinical trials were an invalidating public use. Indeed, experimental use is a key defense for Plaintiffs against that assertion. The prejudice to Plaintiffs of excluding such evidence would far outweigh any prejudice to Barr of a delay in the trial.[1]

CONCLUSION

This case should not go to trial on the basis of a legally incorrect reduction-to-practice date. To do so would reward Barr for its improper conduct. Instead, Barr's motion should be denied.

[1] Plaintiffs dispute that Barr is "currently scheduled" to receive final FDA approval in September 2008, (*see* Barr Mot. at 3), since Barr does not yet have tentative approval.

ASHBY & GEDDES

/s/ John G. Day

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Dated: May 2, 2008

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	:	Civil Action
Plaintiffs,	:	
v.	:	
BARR LABORATORIES, INC.,	:	
Defendant.	:	No. 06-286-GMS

- - -

Wilmington, Delaware
Thursday, April 24, 2008
9:30 a.m.
Conference

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

APPEARANCES:

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TIFFANY GEYER LYDON, ESQ.
Ashby & Geddes
-and-
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(Chicago, Illinois)

Counsel for Defendant

not getting to it, you will be materially prejudiced.

MR. HURST: The answer, unfortunately, Your Honor --

THE COURT: You will be materially prejudiced.

MR. HURST: This is how big the issue is. It is a huge issue for us, because if --

THE COURT: Can I ask why a motion in limine wasn't filed?

MR. HURST: Because it just came up on Monday. We just learned on Monday.

This is the issue, Your Honor. On Monday, Aventis served a supplemental interrogatory response, changing their claimed date of reduction to practice by two years, from May of 1992 to April of 1994.

THE COURT: So ruling on this is going to materially affect the presentation?

MR. HURST: Yes. But even more importantly, I would think, is this. At the beginning of the case, we asked, what is your date of reduction to practice? Because, as you know, in a patent case, that drives a lot. So we asked. And we got a date that we thought was great for us, frankly.

And we didn't challenge it through discovery. We didn't interrogate their witnesses on their date of reduction to practice. We didn't consider using expert

EXHIBIT B

REDACTED

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-286-GMS
BARR LABORATORIES, INC.,	)	
Defendant.	)	

PLAINTIFFS' FIRST SET OF INTERROGATORIES TO DEFENDANT BARR LABORATORIES, INC. (NOS. 1-8)

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Aventis Pharmaceuticals Inc. and Sanofi-Aventis US LLC ("Plaintiffs") propounds the following Interrogatories to Defendant Barr Laboratories, Inc. ("Barr"). The written responses to these Interrogatories shall be served upon Plaintiffs' counsel within thirty (30) days of the receipt hereof. Further, any documents and things produced in response to these Interrogatories shall be produced for inspection and copying at the offices of McDonnell, Boehnen, Hulbert, & Berghoff LLP, 300 South Wacker Drive, Chicago, Illinois, 60606, within thirty (30) days of the receipt of these Interrogatories.

DEFINITIONS

For purposes of responding to these requests for production of documents, the following definitions shall apply:

1. The term "Plaintiffs" shall mean Aventis Pharmaceuticals Inc., Sanofi-Aventis US LLC; their predecessors, parents, subsidiaries, divisions, affiliates, officers, directors, employees, agents, distributors, jobbers, salepersons, interns, sales

representatives, and attorneys; and each person acting or purporting to act on its or their behalf or under its or their control.

2. The term "Defendant," and "Barr" shall man Defendant Barr Laboratories Inc. and any other company name under which Barr is doing or has done business; its predecessors, parents, subsidiaries, divisions, licensees, franchisees, assigns or other related business entities; their directors, officers, employees, agents, distributors, jobbers, salespersons, interns, and attorneys; and each person acting or purporting to act on its or their behalf or under its or their control.

3. The terms "person" and "persons" shall mean natural persons (including those employed by Defendant) and all other legally cognizable entities, including (without limitation) governmental entities, agencies, officers, departments, or affiliates of any other governmental entity; commercial entities, corporations, foundations, partnerships, proprietorships, associations; and other non-governmental organizations.

4. The term "date" shall means the exact day, month and year, if ascertainable, or, if not, Defendant's closest approximation (including by description of the date in relation to other events).

5. The terms "documents" and "things" shall have the broadest scope permissible under the Federal Rules of Civil Procedure and shall include (without limitation) the originals (or, absent any original, a copy) of any writings or other tangible things, however produced or reproduced, including books, accounting and financial records of any nature whatsoever, agreements, communications, correspondence, e-mail, telegrams, cables, telexes, telecopy or fax transmission messages, memoranda, video, audio or other electromagnetic recordings, studies, summaries or records of telephone

conversations, summaries or records of personal conversations or interviews, diaries, letters, forecasts, statistical statements, graphs, laboratory or engineering reports and records, notebooks, charts, plans, sketches, drawings, information bearing photographic products of any nature whatsoever, photo-records, microfilms, minutes or records of meetings or conferences, expressions or statements of policy, lists of persons attending meetings or conferences, reports and/or summaries of interviews, reports and/or summaries of investigations, opinions or reports of consultants, patent appraisals, patent searches, opinions of counsel, records, reports or summaries of negotiations, sales literature of any nature whatsoever, brochures, catalogues, catalogue sheets, pamphlets, periodicals, advertisements, circulars or trade letters, press releases, publicity releases, new product releases, reprints, drafts of any documents, working papers, indices, original or preliminary notes, computer printouts and other data compilations from which information can be obtained or translated, if necessary, by Defendants through detection devices into reasonably usable form. Any copy of a "document" as described above containing thereon or attached thereto any alteration, notes, comments or other mark, indicia, or material not included in the original or copy referred to in the preceding sentence shall be deemed a separate "document" within the foregoing definition. The terms "documents" and "things" shall also mean tangible objects other than "documents" as described above, and shall include objects of every kind and nature such as, but not limited to, prototypes, models and specimens. The terms "document" and "things" shall refer to any of the above-identified objects in any tangible form, including electronic versions maintained in a magnetic or optical storage medium.

6. The term "communication" shall mean any transmission of information from one person or entity to another, including (without limitation) by personal meeting, telephone, facsimile, radio, telegraph, electronic mail, teleconference, writing, or other means.

7. The terms "referring," "relating" and "concerning" shall be interpreted as broadly as possible so as to encompass the liberal scope of discovery set forth in Rule 26(b) of Fed. R. Civ. P.

8. The terms "identify," "identification," "describe," and "description" shall mean to provide a complete identification of the document, thing, or person to the fullest extent known or ascertainable by Barr, whether or not the information is in the possession, custody, or control of Barr and whether or not the information is alleged to be protected by any privilege or work product protection, and includes without limitation a request for the following information:

(a) with respect to a natural person, his or her name, home and work addresses, home and work telephone numbers, present place of employment (or if unknown, the last known), date(s) of commencement and termination of employment, job title, and description of his or her duties and responsibilities;

(b) with respect to a person other than a natural person, the full name, state of incorporation or registration, address of its principal place of business, telephone number of its principal place of business, and the identity of each natural person who acted on behalf of such entity with respect to the subject matter of the Request;

(c) with respect to a document, the type of document (e.g., letter, e-mail, facsimile, contract, calendar pad, report); the number of pages of which the document consists, a description of the document's contents; an identification of each natural person who prepared the document; an identification of each natural person for whom it was prepared; each natural person who signed it; an identification of each natural person to whom it was delivered, mailed, or otherwise received; an identification of each natural person to whom a copy was sent or who otherwise received a copy; the date of writing, creation, and publication; identifying number(s), letter(s) or combination thereof, if any; the significance or meaning of such number(s), letter(s) or combination thereof; and present location and identity of the custodian of that document. Documents to be identified shall include documents currently in Barr's possession, custody or control; documents Barr knows to have once existed but that no longer exist; and other documents of which Barr has knowledge or information but that are not currently in its possession, custody, or control;

(d) with respect to oral communications, the manner in which the communications were made (telephone, conversation, etc.); the identity of each natural person who participated in or witnessed the communication; the subject matter and content of the communication; and the date of the communication;

(e) with respect to a patent or patent application, the country or jurisdiction in which it was filed, number, named inventor(s), filing date, issue date (if a patent), and all related or foreign counterpart applications and patents; and

(f) with respect to films, photographs, tapes, computer media, and other things susceptible to chemical, biological, mechanical, or electrical reproduction, all identifying information including their character, subject matters, authors, and dates.

9. The terms "and," "or," and "and/or" shall be construed disjunctively or conjunctively as necessary to bring within the scope of these Requests all responses which otherwise might be construed to be outside its scope.

10. The terms "describe" and "state" shall mean to set forth fully and unambiguously every fact relevant to the subject of the Request of which Barr has knowledge or information.

11. Any word written in the singular herein shall be construed as plural or *vice versa* as necessary to bring within the scope of these Requests all responses which otherwise might be construed to be outside its scope.

12. The "'573 patent" shall mean U.S. Patent No. 5,976,573.

13. The "'329 patent" shall mean U.S. Patent No. 6,143,329.

14. "Patents-in-suit" shall mean U.S. Patent No. 5,976,573 and U.S. Patent No. 6,143,329 collectively.

15. "FDA" shall mean the U.S. Food and Drug Administration.

16. "Barr's ANDA" shall mean Abbreviated New Drug Application No. 78-104.

17. "Barr's ANDA Product" shall mean the drug product in Abbreviated New Drug Application No. 78-104.

18. The term "prior art" includes by way of example and without limitation, any subject matter that Barr assert may be encompassed by 35 U.S.C. § 102 and/or 35 U.S.C. § 103.

19. No interrogatory or subpart hereof shall be construed as a limitation on any other request or subpart thereof.

INSTRUCTIONS

1. If Barr produces responsive documents pursuant to Federal Rule of Civil Procedure 33(d), the original and each non-identical copy of each document or other tangible thing requested herein which is in Barr's possession, custody or control (including all copies in the possession, custody, or control of any entity defined as being "Barr") is to be produced, including company, department, and personal files. If the original or copy is not in Barr's possession, custody or control, a full, clear, legible copy thereof is to be produced.

2. If any portion of any Interrogatory refers or relates to information of which Barr was once aware but is no longer within its knowledge, Barr is requested to identify the name, telephone number, and address of the person last known by Barr to have knowledge of such information.

3. Each Interrogatory shall be responded to fully unless it is in good faith objected to, in which event every reason for Barr's objection shall be stated in detail. If an objection pertains to only a portion of an Interrogatory, or a word, phrase, or clause contained within it, Barr is required to state its objection to that portion only and to respond to the remainder of the Interrogatory, using its best efforts to do so.

4. If Barr produces responsive documents pursuant to Federal Rule of Civil Procedure 33(d), each document and thing produced is to be (i) identified in Barr's written response hereto to correspond with the categories of the Request in response to which it is being produced or (ii) produced as it is kept in the usual course of business, including all file folders, binders, notebooks and other devices by which each such document or thing is organized or separated.

5. If Barr or Barr's counsel assert that any information identified in response to an Interrogatory is privileged or otherwise protected from discovery (*e.g.*, by work product immunity), set forth in Barr's response hereto with respect to all information for which a claim of privilege is made such that the document or thing is not produced in full:

a. The place, approximate date, and manner of recording, creating or otherwise preparing any document or thing;

b. The name and organizational position, if any, of each sender of any document or thing;

c. The name and organizational position, if any, of each recipient and/or custodian of any document or thing;

d. The name and organizational position, if any, of each person (other than stenographic or clerical assistants) participating in the preparation or creation of any document or thing;

e. The name and organizational position, if any, of each person to whom the contents of the information or any portion thereof have heretofore been communicated by copy, exhibition, reading or summarization;

f. A statement of the basis on which privilege is claimed with respect to the information and including a statement of sufficient relevant facts and circumstances that will explain the basis of the claim of privilege and will permit the adjudication of the propriety of the claim of privilege;

g. The name of each person, other than Barr's attorneys of record, having knowledge of the factual basis asserted for the privilege claim;

h. The number of the Interrogatory to which the document or thing is responsive;

i. The identity and organization position, if any, of each person supplying the author of Barr's response hereto with the information requested in subsections (a) through (g) above;

j. The type of any document or thing withheld (e.g., letter, memorandum, etc.);

k. The subject matter of any document, communication, or other information;

l. The location(s) where, if at all, information has been redacted on any document or thing thus produced;

m. The location of any document, communication, thing or other information withheld; and

n. In the case of a document, the length of the document in number of pages.

6. The Interrogatories seek all information Barr knows as of the date of service hereof, unless otherwise stated in a particular Interrogatory. Pursuant to Federal

Rule of Civil Procedure 26(e), these Interrogatories are deemed to be continuing so that with respect to any Interrogatory, or part thereof, as to which Barr, after answering, acquire additional documents or things or knowledge or information, Barr shall seasonably serve supplemental responses and/or make a supplemental production of documents and things, in no case later than thirty (30) days after acquiring such additional documents or things or knowledge or information.

INTERROGATORIES

INTERROGATORY NO. 1

Identify and describe in detail all natural persons having responsibility for the research and development, manufacture, or importation of Barr's ANDA product or any other Barr TAA product including, without limitation, by identifying the role that each such individual had in the research and development, manufacture, offer for sale, sale, and importation of Barr's ANDA product or any aqueous nasal product containing triamcinolone acetonide.

INTERROGATORY NO. 2

Identify each opinion, whether written or non-written, that Barr has requested and/or received regarding any issue with respect to any of the patents-in-suit or which discusses in any manner any of the patents-in-suit, and, for each such opinion, identify each person that has reviewed or otherwise been informed as to the substance of the opinion, identify each person who has relied upon the substance of the opinion (if any), describe in detail how each identified person relied upon the substance of the opinion,

and identify all dates, persons, places and documents that relate to such opinion (e.g., including but not limited to the date when drafted, date when communicated to any individual, and locations where copies of each such opinion can be found), and identify all documents that relate or refer to such opinion.

INTERROGATORY NO. 3

Identify each person involved in any evaluation of any of the patents-in-suit conducted by or on behalf of Barr, including but not limited to any evaluation of validity, infringement, enforceability, scope or value of any of the patents-in-suit and describe in detail the nature and subject of the evaluation performed by each such person and identify all documents that relate to such evaluation.

INTERROGATORY NO. 4

Identify all persons involved in Barr's decision to file an ANDA or any other application for regulatory approval for, to manufacture, to import, to sell or to offer for sale Barr's ANDA product or any aqueous nasal product containing triamcinolone acetonide and describe in detail each such person's involvement and all facts and documents considered in making such decisions.

INTERROGATORY NO. 5

Identify all facts and evidence supporting the contentions in Barr's Third Affirmative Defense and Counterclaims I and III that the patents-in-suit are "invalid under one ore more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112," including by

identifying each claim of the patents-in-suit that Barr contends is invalid; providing for each such claim a claim chart including, but not limited to, a detailed explanation as to why each element of each claim is disclosed by any prior art reference or references and/or prior art fact or facts; identifying the specific location of such alleged disclosure or disclosures; identifying any documents, communications (whether oral or written), or things containing such facts or evidence; and identifying all persons at or on behalf of Barr with knowledge concerning such non-infringement contentions.

INTERROGATORY NO. 6

Identify all facts and evidence supporting the contentions in Barr's Fourth Affirmative Defense and Counterclaims II and IV that Barr's ANDA Product does not infringe one or more claims of the patents-in-suit, including by identifying each claim of the patents-in-suit that Barr contends does not or would not be infringed by Barr's ANDA Product and/or the manufacture, use, sale and/or offer for sale of Barr's ANDA Product; providing for each such claim a claim chart including, but not limited to, a detailed explanation as to all elements of each claim that are not present in Barr's ANDA and/or Barr's ANDA product; identifying any documents, communications (whether oral or written), or things containing such facts or evidence; and identifying all persons at or on behalf of Barr with the most knowledge concerning such non-infringement contentions.

INTERROGATORY NO. 7

Identify each and every entity with which Barr had or has a relationship, whether by contract, agreement, license, informal arrangement or otherwise, relating to triamcinolone acetonide, any aqueous nasal product containing triamcinolone acetonide,

and/or Barr's ANDA product, including a description of the nature and terms of the relationship, the date on which the relationship began (as best as can be identified), the person(s) involved in negotiating and/or maintaining the relationship, and all documents which led up to, define, describe, relate to, or refer to that relationship.

INTERROGATORY NO. 8

Identify each person whom Barr expects to call at trial, in whole or in part, as a fact witness, and for each such witness identify the subject matter upon which the witness is expected to testify, the substance of the facts as to which the witness is expected to testify, and each document or other evidence or communication upon which the witness is expected to rely in presenting his or her testimony.

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Dated: September 8, 2006
172958.1

CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of September, 2006, the attached **PLAINTIFFS' FIRST SET OF INTERROGATORIES TO DEFENDANT BARR LABORATORIES, INC. (NOS. 1-8)** was served upon the below-named counsel of record at the address and in the manner indicated:

Josy W. Ingersoll, Esquire — HAND DELIVERY
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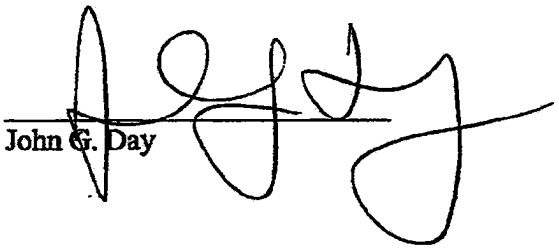

John G. Day

169789.1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-286-GMS
BARR LABORATORIES, INC.,	)	
Defendant.	)	

NOTICE OF SERVICE

The undersigned hereby certifies that on the 8th day of September, 2006, **PLAINTIFFS' FIRST SET OF INTERROGATORIES TO DEFENDANT BARR LABORATORIES, INC. (NOS. 1-8)** was served upon the following counsel of record at the address and in the manner indicated:

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Dated: September 8, 2006
172717.1

CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of September, 2006, the attached **NOTICE OF SERVICE** was served upon the below-named counsel of record at the address and in the manner indicated:

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/s/ *John G. Day*

John G. Day

EXHIBIT D

REDACTED

EXHIBIT E

REDACTED

EXHIBIT F

REDACTED

EXHIBIT G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC	)	
Plaintiffs,	)	
v.	)	C.A. No. 06-286 (GMS)
BARR LABORATORIES, INC.	)	
Defendants.	)	

REBUTTAL EXPERT REPORT OF MICHAEL A. KALINER

I, Michael A. Kaliner, M.D., declare as follows:

1. Since submitting my expert report, I have reviewed the expert reports of Dr. Maureen D. Donovan and Dr. Thomas E. Needham submitted in this case. I have also considered the documents set forth in the exhibit hereto. All other information set forth in my opening report remains accurate.

Barr's Invalidity Defenses

2. I have been informed that Barr has asserted several invalidity defenses, including the following:

a. that the asserted claims of the '573 and '329 patents are invalid as anticipated because the aqueous triamcinolone acetonide nasal spray that is the subject of the '573 and '329 patents was publicly used in clinical trials before July 3, 1995;

b. that claim 13 of the '329 patent is invalid as anticipated by the 1995 Physician's Desk Reference as a printed publication;

c. that claim 25 of the '329 patent is invalid as anticipated by either Guy Settipane *et al.*, Triamcinolone Acetonide Aqueous Nasal Spray in Patients with Seasonal Ragweed Allergic Rhinitis: A Placebo-Controlled, Double-Blind Study, 17 Clinical Therapeutics 252-63 (1995), or Roger H. Kobayashi *et al.*, Triamcinolone Acetonide Aqueous Nasal Spray for the Treatment of Patients with Perennial Allergic Rhinitis: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study, 17 Clinical Therapeutics 503-13 (1995), as a printed publication;

d. that the asserted claims of the '573 and '329 patents are invalid as obvious in view of prior art, including the knowledge of a person of skill in the art and the following references and products:

i. Guy Settipane *et al.*, Triamcinolone Acetonide Aqueous Nasal Spray in Patients with Seasonal Ragweed Allergic Rhinitis: A Placebo-Controlled, Double-Blind Study, 17 Clinical Therapeutics 252-63 (1995);

ii. Roger H. Kobayashi *et al.*, Triamcinolone Acetonide Aqueous Nasal Spray for the Treatment of Patients with Perennial Allergic Rhinitis: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study, 17 Clinical Therapeutics 503-13 (1995);

iii. 1995 Physicians' Desk Reference and Supplements;

iv. 1996 Physicians' Desk Reference and Supplements;

v. Handbook of Pharmaceutical Excipients;

vi. United States Patent No. 4,767,612;

vii. International Publication No. WO 92/14473;

viii. International Publication No. WO 92/04365;

ix. International Publication No. WO 94/05330;

x. 1990-95 Avicel Product Brochures;

xi. Nasacort® Nasal Inhaler;

xii. Beconase AQ®;

xiii. Vancenase AQ®;

xiv. Flonase®;

xv. Nasalide®;

xvi. A. K. Pennington *et al.*, The Influence of Solution Viscosity on Nasal Spray Deposition and Clearance, 43 International Journal of Pharmaceutics 221-24 (1988);

xvii. H. Alice Orgel *et al.*, Clinical, Rhinomanometric, and Cytologic Evaluation of Seasonal Allergic Rhinitis Treated with Beclomethasone Dipropionate as Aqueous Nasal Spray or Pressurized Aerosol, 77 Journal of Allergy and Clinical Immunology 858-64 (1986); and

xviii. R. M. E. Richards & R. H. Cavill, Electron Microscope Study of Effect of Benzalkonium Chloride and Edetate Disodium on Cell Envelope of Psuedomonas aeruginosa, 65 Journal of Pharmaceutical Sciences 76-80 (1976).

e. that the asserted claims of the '573 and '329 patents are invalid for lack of enablement because the patent specification fails to enable a person of skill in the art to make a formulation that deposits on all of the claimed regions of the nasal cavity;

f. that claims 21-35 of the '573 patent are invalid for lack of enablement and/or written description because the patent specification fails to enable a person of skill in the art to make a formulation that remains in the frontal sinus for at least about an hour.

Legal Standards for Invalidity Arguments

3. I have been informed that patent claims are presumed valid, but can be shown to be invalid by clear and convincing evidence. I have also been told that the validity of each claim must be considered independently.

4. I have been informed that, in relation to a contention that patent claims are invalid as anticipated by a public use, the patent claims are valid unless the invention was in public use more than one year prior to the date of the application for patent in the United States. I have been informed that the date for determination of whether a "public use" could invalidate the claims of the '573 and '329 patents is July 3, 1995. I have been informed that a "public use" is one by a person who is not under any limitation, restriction, or obligation of secrecy to the inventor.

5. I have been informed that an "experimental use" is not a "public use." I understand a use is "experimental use" if it was done for a *bona fide* experimental purpose, to perfect the invention, rather than for commercial exploitation. I understand that factors in determining whether a use is "experimental" include: (1) the necessity for public testing; (2) the amount of control over the experiment retained by the inventor (or his agent); (3) the nature of the invention; (4) the length of the test period; (5) whether payment was made; (6) whether there was a secrecy obligation; (7) whether records of the experiment were kept; (8) who conducted the experiment; (9) the degree of commercial exploitation during testing; (10) whether the invention reasonably required evaluation under actual conditions of use; (11) whether testing was systematically performed; (12) whether the inventor (or his agent) continually monitored the invention during testing; and (13) the nature of contacts made with potential customers.

36. I do not believe that the Kobayashi *et al.* article identifies how to make the TAA Aqueous product described therein. The only portion of the formulation that the article identifies is triamcinolone acetonide, and none of the inactive excipients is identified. I understand that Dr. Robert Lochhead is of the opinion that a person of ordinary skill in the art would also not necessarily know how to make the TAA Aqueous product from the description in the article. As a result, in my opinion, the Kobayashi *et al.* article does not anticipate claim 25 of the '329 patent because would not have enabled one of skill in the art to make the TAA Aqueous product.

Confidentiality of Clinical Trials

37. I have been informed, as set forth in paragraph 2 above, that Barr contends that the asserted claims of the '573 and '329 patents are invalid as anticipated because the aqueous triamcinolone acetonide nasal spray that is the subject of the '573 and '329 patents was publicly used in clinical trials before July 3, 1995. Specifically, I understand that Barr contends that the Phase III clinical trials of aqueous triamcinolone acetonide nasal spray discussed in the Settipane *et al.* and Kobayashi *et al.* articles constituted a "public use" of that product. While Settipane *et al.* and Kobayashi *et al.* articles discussed the clinical trials, however, they were not part of them because they reported the results after the trials were completed. Under the circumstances, and according to the legal standards set forth above, I believe that the Phase III clinical trials of aqueous triamcinolone acetonide nasal spray were an experimental use, not a public use.

38. To my understanding as a physician, the FDA generally requires certain clinical trials to be performed on a new drug, new formulation, or new device before the product can be marketed. Clinical trials give the FDA "real world" evidence in determining whether a drug is safe and effective. Clinical trials are generally categorized as Phase I, Phase II, Phase III, or Phase IV; Phase I, II, and III trials occur before the FDA approves a product for marketing,

Phase IV trials occur after approval. I am personally familiar with Phase III trials, having administered them. I am also familiar with Phase I and II trials, having designed them.

39. Phase I, II, and III trials provide various indications of the safety and efficacy of drugs. Phase I trials are usually performed on a small group of patients to determine the safety and tolerability of the product. They can also help determine pharmacokinetics, pharmacodynamics, and dose-ranging. Phase II trials are usually performed on a somewhat larger group of patients to determine efficacy and to continue to determine safety of the product. Phase III trials are performed on a still larger group of patients, usually at several locations and against a placebo or accepted treatment. They help determine if the drug presents safety or efficacy issues in idiosyncratic patients, as well as helping definitively determine the safety and efficacy of the drug in the general population. All three phases involve promises of confidentiality by the doctors or clinics administering them. Clinical investigators receive only very brief description about the studied drug formulation, patient receive even less of a description.[1]

40. Phase III trials are performed on "investigational" or experimental drugs that have not received FDA approval. Many of the drugs studied in Phase III trials never receive FDA approval, whether because of lack of efficacy, safety concerns, or failure to prove greater effectiveness and safety than drugs already on the market. In fact, according to Tamara Elias *et al.*, Why Products Fail in Phase III, In Vivo (Apr. 2006), of 656 screened Phase III trials between 1990 and 2002, 278 (or 42%) failed Phase III trials. Elias, p. 1. Of the 73 compounds for which publicly available information allowed them to do so, the authors determined

> In a full 50% of cases, the drugs in question failed for lack of efficacy: the trials could not demonstrate that the drugs were more medically effective than the placebos. Another 30% of the failures came from safety concerns. In the final

[1] Patients must be provided some information regarding the product to ensure they can provide informed consent and avoid drug interactions. However, the information provided to patients in Phases I, II, and III tends to be significantly more limited than that in the final approved package insert.

> 20%, the new drugs could not be proven safer or more effective than the drugs already on the market.

Elias, pp. 1-2. The authors were astonished by the high percentage of failures for lack of efficacy (and that such efficacy failures occurred across the therapeutic board), given that Phase II trials are intended to help establish efficacy. Elias, p. 1. I am less surprised; in my experience, larger, multi-center trials can generate more accurate efficacy data because they avoid local effects, single-site selection effects, and skewed results due to idiosyncratic patients. Failure of clinical trials due to lack of efficacy is a problem that has been seen in intranasal steroids. Fisons reported it stopped development of a tipredane product intended for the treatment of asthma and rhinitis after trials in several countries demonstrated that the drug "had simply not been effective." Company News; Shares of Fisons Tumble as Company Halts Asthma Drug, N.Y. Times, April 7, 1993, http://query.nytimes.com/gst/fullpage.html?res=9F0CE6DB133EF934A35757C0A965958260. I am also familiar with the failures in Phase III trials of doxepin and capsaicin nasal sprays products, both of which were intended for use for treatment of rhinitis. There have been many other failures of nasal spray products in clinical trials.

41. For allergy products, Phase II and III clinical trials must be performed in a manner that would allow exposure to allergens because without exposure to allergens, it would be impossible to determine if the drugs were successful in diminishing allergy symptoms. That is, those trials cannot take place in a controlled environment. As a practical matter, that means that Phase II and III clinical trials are carried out in part outside the clinic.

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I declare under penalty of perjury that the foregoing if true and correct. Executed on January 30, 2008.

Michael A. Kaliner, M.D.

EXHIBIT H

REDACTED

EXHIBIT I

REDACTED

EXHIBIT J

REDACTED

EXHIBIT K

REDACTED

EXHIBIT L

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EXHIBIT M

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